

from each container. Dilute with sufficient solution 6 to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

(2) *Sterility*. Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens*. Proceed as directed in § 436.32(a) of this chapter, using a solution containing 20,000 units of polymyxin B per milliliter.

(4) [Reserved]

(5) *Loss on drying*. Proceed as directed in § 436.200(b) of this chapter.

(6) *pH*. Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 5 milligrams per milliliter.

(7) *Residue on ignition*. Proceed as directed in § 436.207(a) of this chapter.

(8) *Heavy metals*. Proceed as directed in § 436.208 of this chapter.

(9) *Identity*. (i) To a solution of 2 milligrams of polymyxin B sulfate in 5 milliliters of water, add 0.5 milliliter of triketohydrindene solution (1:1,000) and 2 drops of pyridine, boil for 1 minute, and cool; a blue color develops; and

(ii) To a solution of 2 milligrams of polymyxin B sulfate in 5 milliliters of water, add 5 milliliters of sodium hydroxide solution (1:10), mix well, and add, dropwise, 5 drops of cupric sulfate solution (1:100), mixing after the addition of each drop; a reddish-violet color is produced.

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#### § 448.75 Tyrothricin.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Tyrothricin is a white to brownish-white compound of a kind of tyrothricin or a mixture of two or more such compounds. It consists principally of gramicidin and tyrocidine. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms and not more than 1,400 micrograms of tyrothricin per milligram.

(ii) Its loss on drying is not more than 5 percent.

(iii) It gives a positive identity test for tyrothricin.

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples*. In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, loss on drying, and identity.

(ii) Samples required: five packages, each containing approximately 300 milligrams.

(b) *Tests and methods of assay—(1) Potency*. Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 95 percent ethyl alcohol, U.S.P. XVIII or equivalent, to give a stock solution of convenient concentration. Further dilute the stock solution with 95 percent ethyl alcohol, U.S.P. XVIII or equivalent, to the reference concentration of 0.20 microgram of tyrothricin per milliliter (estimated). Average the absorbance values for the tyrothricin sample and read the gramicidin concentration from the gramicidin standard response line. Multiply by 5 to obtain the number of micrograms of tyrothricin in the sample.

(2) *Loss on drying*. Proceed as directed in § 436.200(b) of this chapter.

(3) *Identity*. To 5 milliliters of *p*-dimethylaminobenzaldehyde (T.S.) add about 5 milligrams of tyrothricin. Shake well for 2 minutes; then add 2 drops of 0.1M sodium nitrite and 5 milliliters of water. A blue color is produced.

#### Subpart B—Oral Dosage Forms

##### § 448.121 Colistin sulfate for oral suspension.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity*. Colistin sulfate for oral suspension is a dry mixture of colistin sulfate, with or without one or more suitable and harmless buffer substances, suspending and dispersing agents, diluents, colorings, and flavorings. The colistin sulfate content is 5.0 milligrams of colistin per milliliter of the reconstituted suspension. Its potency